(b) the contraceptives which do not have any ill-effect on health and reproduction capability; and

(c) for how long the constant use of such drugs is safe from the health point of view?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) and (b) There is no scientific evidence that long term use of contraceptive reduces the reproductive capacity. The Indian Council of Medical Research has since 1972 evaluated a number of contraceptive preparations for their efficacy, safety and return of fertility, and only those preparations which were found suitable have been recommended for use in the country.

(c) All the contraceptives (spacing or terminal) available in the National Family Welfare Programme are safe for long term use. These contraceptives are reviewed and approved by the Toxicology Review Panel, Ethical Committee of the Indian Council of Medical Research, and the Drugs Controller General of India prior to carrying out clinical trials for their efficacy, safety and acceptability.

Drug permission to DGCI

2053. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the permissions granted by the DGCI for new drugs is much less as compared to the permission granted in 2002;

(b) the names of the drugs and companies approved during the period January, 2002 to November, 2003; and

(c) the new combinations permitted during the same period alongwith the names of the companies?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) Approval of new drugs is a complex process, and it varies according to the nature of the molecule/drug. Therefore, depending upon the nature of the application, time taken for approval varies. Approval of new drugs is also subject to the subsmission of all required data as per provisions of the Drugs and Cosmetics Rules.

Certain critical drugs e.g. anticancer, anti-HIV etc., which are important from the point of view of public health are however cleared on fast track basis.

In the year 2002 (from January to December) 53 New Drugs were approved and from January to November 2003, 35 New Drugs have been approved by the DCG(I).

(b) Names of the approved New Drugs during January 2002 to November 2003, along with names of the companies is enclosed at Statement *(See* below)

(c) Names of the New Combinations permitted during the same period along with names of the companies is enclosed at Statement-II. (See below).

Statement-I

List of approved new drugs-from January 2002 to November 2003

1.	Bimatoprost (Ophthalmic Sol.)	Anti-Glaucoma	M/s. Allergan India Ltd
2.	Meropenem Injection	B-lactum Antibiotic	M/s. Astra Zeneca
3.	Fosinopril Sodium	Anti-hypertensive	M/s. Cadila Pharma
4.	Divalproax Sodium	Anti-epileptic	M/s. Cadila Health
5.	Zaleplon	Sedative-Hypnotic	M/s. Torrent Pharma
6.	Thymogen Inj.	Anticancer	M/s. Nicholas M/s
7.	Montelukast Sodium	Anti-asthamatic	Ranbaxy Lab.
8.	Mifepristone	Progesteron antagonist	M/s. Cadiia Health Care
9.	Dexarazoxane inj.	Cardio-protective	M/s. Ambalal Sarahai
10.	Tranexamic acid	Antifibrolytic	M/s. Macleod Pharma
11.	Bicalutamide	Anticancer	M/s. Cipla Ltd.
12.	Loteprednol etabonate	Ophthalmic	M/s.Sun Pharmaceu-ticals
13.	Apraclonodone	Ophthalmic	M/s. Cipla Ltd.
14.	Mizoiastine	Antiallergic	Dr. Reddy's Lab.
15.	Ziprasidone	For Schizophrenia	M/s. Torrent Pharma
16.	Miltefosine	For Kala-Azar	M/s. German Remedies
17.	Abacavir	Anti HIV	M/s. Hetero Drugs

18.	Nadifloxacin	Antibacterial	M/s. Wockhardt Ltd.
19.	Tamsulosin	For BPH	M/s. Cipla Ltd.
20.	Famciclovir	Anti-viral	M/s. Cipla Ltd.
21.	Nateglinide	Antidiabetic	M/s. Alembic Lab.
22.	Lercanidipine	Antihypertensive	M/s. Sun Pharma-ceuticals
23.	Itopinde	Prokinetic agent	M/s. Knoll Pharma
24.	Alprostadil inj.	For ED in men	M/s. Pharmacia India
25.	Vimpocetine	Vasodilator	M/s. Sun Pharma-ceuticals.
26.	Quitapine fumarate	Antipsychotic	M/s. Sun Pharma-ceuticals.
27.	Isotretinoin	For Acne	M/s. Shalaks Pharma
28.	Nebivolol	Antihypertensive	M/s. Sarvottam Care
29.	Sirolimus	Immunosuppressant	M/s. Wyeth Lederle
30.	Drotrecogin Alpha	For Severe sepsis	M/s. Eli Lilly
31.	Pygenum africum	For BPH	M/s. Banner Pharma
32.	Valdecoxib	NSAID	M/s. Glenmark Pharma.
33.	Thalidomide	For Leprosy	M/s. Dabur India
34.	S-Amlodipine	Antihypertensive	M/s. Emcure Pharma
35.	Cabergoline	For hyperprolactemia	M/s. Sun Pharma-ceuticals
36.	Butarphenol tarterate	Opoid analgesic	M/s. Aristo Pharma
37.	Gemtuzumab	For Myeloid Leukemia	M/s. Wyeth Lederle
38.	Quinapril	Antihypertensive	M/s. Macleod Pharma
39.	Valacyclovir	Anti-viral	M/s. Cipla Ltd.
40.	Fosphenytoin	Anti-epileptic	M/s. Cadila Health Care
41.	Ceftiofur sod.	Antibiotic (Vet use)	M/s. Aurobindo Pharma
42.	Metaxalone	Muscle relaxant	M/s. Sun Pharma-ceuticals
43.	Meglumine gadoteric	Contrast Media	M/s. Imaging Products
44.	Cefepine hcl	Antibiotic	M/s. Aurobindo Pharma
45.	Acamproste calcium	For alcohol dependency	M/s. Sun Pharma-ceuticals
46.	Aztreonam	Antibacterial	M/s. Aurobindo Pharma

47.	Tegaserod	For IBS	M/s. Torrent Pharma.
48.	Parecoxib	NSAID	M/s. Glenmark Pharma
49.	Balsalezide	For ulcerative colitis	M/s. Torrent Pharma.
50.	Cefetemat-prioxil	Antibacterial	M/s. Alembic Ltd.
51.	Telmiadan	Antihypertensive	M/s. Glenmark Pharma
52.	Levocetrizine	antihistaminic	M/s. Hetero Drugs.
53.	Poractant alpha	For respiratory distress	M/s. Nicholas
54.	Cefprozil	Antibiotic	M/s. Ranbaxy Ltd.
55.	Cilostazol	For intermittent claudication	M/s. Glenmark Pharmaceuticals
56.	EscitaloprarnOxalate	Anti depressant	M/s. Sun Pharma
57.	Anastrazole	Anti cancer	M/s. Astrazeneca
58.	Rizapriptan	Anti migrain	M/s. Cipla Ltd.
59.	Gadobenate (Dimeglumine IV Injection)	MRI Contrast Medium	
60.	Tacrolimus Ointment	Immuno-modulator	M/s. Glenmark Pharma
61.	Metolazone	Diuretic	M/s. Cadila Healthcare
62.	Tiotropium Boromide	Anti asthematic	M/s. Cipla Ltd.
63.	Gadoversetamide Injection	MRI Contrast Medium	M/s. Tyco Healthcare
64.	Torsamide	Diuretic	M/s. Micro Lab
65.	Cyproterone Tablet	For Prostatic Cancer	M/s. Cipla Ltd.
66.	Aripiprazole	Anti schizophrenia	M/s. Sun Pharma
67.	Azelaic Acid	Anti-Acne	M/s. Micro Lab
68.	Bendrofluazide	Diuretic	M/s. Unichem Ltd.
69.	Imipenem +Cilastatin	Anti-Bacterial	M/s. Ranbaxy Ltd.
70.	Tirofiban HCI I.V	Anti-Platelet	M/s. Cadila Healthcare
71.	Teriparatide	For Osteoporosis	M/s.Eli Lilly & Co.
72.	Cladribine	Anti-Cancer	M/s. Dabur India
73.	Tadalafil	For Erectile Dysfunction	M/s. Eli Lilly
74.	S-Atenolol	Anti-hypertensive	M/s. Emcure Pharma
75.	Rosuvastatin	Lipid lowering Agent	M/s. Astrazeneca
76.	Tazarotene	Anti-Acne	M/s. Glenmark Pharma
77.	Aceclofenac	NSAID	M/s. Intas Pharma

78.	(Dopamine HCl	Opthalmic	M/s. Cadila Pharma
79.	Trandolapril	Anti-Hypertensive	M/s. Hetero Drugs
80.	Dorzolamide	Opthalmic	M/s. Hetero Drugs
81.	Fenoverine	Anti-spasmodic	M/s. Micro Lab
82.	Risedronate Sodium	For Osteoporosis	M/s. Aventis Pharma
83.	Fondaparinax Sodium	LMWH	M/s. Sanofi Synthelabo
84.	Metadoxine	For Hepatic Disorder	M/s. Sun Pharma
85.	Valgancyclovir	For CMV	M/s. Roche
86.	Isopropyl Unoprostone	Ophthalmic	M/s. Novartis India
87.	Amorolfine	Anti-Fungal	M/s. Galderma
88.	Fluvastatin Sodium	Lipid Lowering Agent	M/s. Novartis India

Statement-II

List of combinations permitted during January 2002 to November 2003.

Sr. No.	Fixed Dose Combination	Name of Company(ies)
1.	Mometasone furoate + Terbinafin	M/s. Ranbaxy Lab.
2.	Rosiglitazone + Metformin	M/s. Torrent/Glenmark Pharma.
3.	Mosapride + MPS	M/s. Intas Pharma/Ontop.
4.	Formeterol+ Budesonide	M/s. Cipla Ltd.
5.	Butenafine + Betamethasone	M/s. Glenmark Pharma
6.	Amlodipine + Benazapril	M/s. Cipla Ltd.
7.	Sucralfete + Metronidazole	M/s. Starssenburg Pharma
8.	Glycapyrrolate + Neostigmine	M/s. Neon Lab
9.	Betamethasone + Salicylic acid	M/s. Ontop Pharma
10.	Mefenamic acid + Tizanidine	M/s. Blue Cross
11.	Latanoprost + Timolol	M/s. Pharmacia India
12.	Tobramycin + Fluromethalone	M/s. M.J. Pharma.
13.	Betamethasone + Gentamicin	M/s. Ontop Pharma
14.	S- Amlodipine + Losartan	M/s. Emcure Pharma

Sl. No.	Fixed Dose Combination	Name of Company(ies)
15.	S-Amlodipine + Atenolol	M/s. Emcure Pharma
16.	Pioglitazone + Glimeperide	M/s. Ranbaxy Lab.
17.	Glimeperide + Metformin	M/s. Torrent Pharmaceuticals
18.	Rosiglitazone + Glimeperide	M/s. Torrent Pharmaceuticals
19.	Tramadol + Paracetamol	M/s. Cadila Health Care.
20.	Ramipril + s (-) Amlodipine	M/s. Torrent Pharmaceuticals
21.	Olanzapine + Fluoxetine	M/s. Sun Pharamaceuticals
22.	Ciprofloxacin + Ornidzole	M/s. Panacea
23.	Quinapril + HCTZ	M/s. Cipla Ltd.
24.	Aspirin + Dipyridamole	M/s. Intas Pharma.
25.	Cyproterone + Ethinyl Estradiol	M/s. Cadila Health Care
26.	Pioglitazone + Glimeperide	M/s. Glenmark Pharma
27	S-Amlodipine + Lisinopril	M/s. Emcure Pharma
28.	Valsartan + HCTZ	M/s. Novartis India
29.	Montelukast + bambuterol	M/s. Okasa Pharma
30.	Adapeline + Clindamycin	M/s. Glenmark Pharma
31.	Ramipril + Candisartan	M/s. Okasa Pharma
32.	Telmisartan + HCTZ	M/s. Glenmark Pharma
33.	Rofecoxib + Tizanidine	M/s. Torrent Pharmaceuticals
34.	Losartan + Ramipril	M/s. Unichem
35.	Rofecoxib + Paracetamol	M/s. Torrent Pharmaceuticals.
36.	Lamivudine + Zidovudine + Abacavir	M/s. Cipla Ltd.,M/s. Hetero drugs
37.	Nadifloxacin + Clobetasol	M/s. Wockhardt Ltd.
38.	Lercanidipine + Atenolol	M/s. Glenmark Pharma
39.	S-Amlodipine + Valsartan	M/s. Torrent Pharmaceuticals
40.	S- Atenolol + S-Amlodipine	M/s. Emcure Pharma